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A Comparison of Individual Dietary Counseling to a Self-Directed Education Program for Cholesterol Reduction

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The National Cholesterol Education Program has alerted the public to the risks associated with high levels of serum cholesterol. As a result there has been a considerable increase in the number of individuals seeking dietary advice. This increasing client load has raised questions as to the best educational approach or method to use. The objective of this study was to examine the effectiveness of two approaches to nutrition education. The approaches examined were individual dietary counseling and Self-Care for a Healthy Heart (SC)--a self-directed diet education program, developed specifically for this study. One hundred and twenty-two men and women aged 25-79, who had been identified as "at risk" for developing coronary artery disease due to total serum cholesterol levels (TC) in excess of 200mg/dl and/or a TC to HDL-cholesterol ratio (TC/HDL-C) greater than 4.5 took part in this 12 week study. The individuals that received SC had a significant decrease in TC (5.1%), while the individuals assigned to UC demonstrated significant decreases in TC (4.7%) and TC/HDL-C ratio (6.3%). The results of this study suggest that a well designed Self-Care approach has the potential to be a viable alternative to individual counseling.

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A Comparison of Individual Dietary Counseling to a Self-Directed Education Program for Cholesterol Reduction

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A Comparison of Individual Dietary Counseling to a Self-Directed Education Program for Cholesterol Reduction

Abstract. The National Cholesterol Education Program has alerted the public to the risks associated with high levels of serum cholesterol. As a result there has been a considerable increase in the number of individuals seeking dietary advice. This increasing client load has raised questions as to the best educational approach to use. The objective of this study was to examine the effectiveness of two approaches to nutrition education. The approaches examined were individual dietary counseling (UC) and *Self-Care for a Healthy Heart* (SC)--a self-directed diet education program, developed specifically for this study. One hundred and twenty two men and women aged 25-79, who had been identified as "at-risk" for developing coronary artery disease due to total serum cholesterol levels (TC) in excess of 200 mg/dl and/or a TC to HDL-cholesterol ratio (TC/HDL-C) greater than 4.5, took part in this 12 week study. The individuals that received SC had a significant decrease in TC (5.1%), while the individuals assigned to UC demonstrated significant decreases in TC (4.7%) and TC/HDL-C ratio (6.3%) ($P<0.05$). The results of this study suggest that a well designed *Self-CARE* approach has the potential to be a viable alternative to individual counseling.

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INTRODUCTION

Programs designed to identify and/or treat individuals with high serum cholesterol levels at risk for coronary artery disease (CAD) have increased substantially during the last decade. The United States Air Force (USAF) made an early commitment to preventive cardiology when, in 1977, it began the USAF Health Evaluation and Risk Tabulation Program (1) which served as a pilot program and led to the establishment of the USAF Coronary Artery Risk Evaluation (CARE) Program in 1982. Since 1982, the USAF has been aggressively identifying individuals who are at increased risk of developing CAD and has been using a multidisciplined approach to reduce that risk through counseling, education, therapy, and follow-up evaluations (2). The USAF, like many civilian medical facilities, has seen a large increase in the number of individuals being screened and, as a consequence, the number ultimately seeking intervention (3). This increasing patient load has raised questions as to the best approach to use to help lower cholesterol levels and the risk of CAD (4).

Since one-on-one counseling by a physician with a patient is unrealistic both in terms of time and money (5,6), individuals found to be at risk are often referred to other health professionals for dietary intervention, the first step in most CAD risk reduction efforts (7). While the specific shape and content of the intervention is up to the individual clinic, physician, dietitian, or nutrition educator, the large volume of patients and limited health professional resources make it important to determine which types of nutrition education programs are in fact effective.

This study was undertaken with the understanding that the USAF is committed to providing an effective cholesterol intervention program for individuals at risk, while attempting to efficiently use a limited pool of personnel, money, and time. Consequently, the first objective of this study was to assess the effectiveness of the *usual-care* (UC), individual dietary counseling, and of *Self-CARE for a Healthy Heart* (SC), a self-paced nutrition education program designed specifically for the adult learner and this study. The second objective of this study was to determine if the SC program could be considered a viable alternative to UC.

METHODS

This study was carried out at a USAF hospital out-patient clinic serving a population that consisted of active duty individuals, their families, and retired members. At this clinic, a registered dietitian (RD) was in charge of nutrition education. The specific design of this study was a *pretest-posttest* comparison group design (8) where the participants were randomized and assigned to either SC or UC and followed for 12 weeks.

Design and materials development. The SC program was designed to save time and manpower, to specifically meet the needs of the adult learner, and featured a single theme, "reduce your fat intake." An integral part of SC was the PRUCAL diet analysis (9). This analysis, based on a 24-hour diet record, compared the subject's reported diet to the "Prudent Diet" that recommends no more than 30% of the calories as fat, with 10% each from saturated and polyunsaturated fat. In addition, specific recommendations and personalized comparisons were made for energy, cholesterol, dietary fiber, vitamins, and minerals. Three diet analyses were included. The first analysis provided baseline data and was used by the study participant as a reference during completion of the SC program. The second analysis, completed mid-way through the study, was used to provide a means of maintaining contact with the subjects, since it has been reported that self-instruction is not very successful unless periodic contact is maintained (10). The third analysis was used to measure dietary changes over the course of the SC program and for comparison with the final UC dietary analysis.

Each *Step* in the four step SC program was organized in accordance with a model of acceptance of change that divides the way in which adults adopt new ideas into five stages: 1) Awareness, 2) Interest, 3) Evaluation, 4) Trial, and 5) Adoption (11). In addition, each *Step* had specific cognitive, affective, and behavioral outcomes established. Step-1 helped to identify personal risk factors, while Step-2 focused on decreasing dietary fat and cholesterol. Step-3 identified "empty calories" and the value of increasing the intake of complex carbohydrates, and then Step-4 concluded the program by reviewing personal dietary goals, discussing the importance of exercise, and offering points of contact for additional information. Each of the four "Steps" in the SC program used the same four-page format. Page one, titled "WHAT CAN I DO?," developed "awareness" by introducing a new practice or idea using a quiz or example.

Page two, titled "HOW CAN I DO IT?," was designed to increase the *interest* of the reader and help him/her to *evaluate* the suggested changes. Page three was titled "MORE THAT I CAN DO!" and provided the individual with the opportunity to examine the usefulness of the new practice on a *trial* basis. Finally, page four, titled "FACTS...FOR SELF-CARE," was designed to reinforce the new diet habits the individual was to adopt. Some of the information included in the SC program was drawn with permission from other successful educational programs (12-14). After extensive validation of materials, a small pilot study involving ten individuals was completed prior to final printing and subsequent initiation of this study.

The complete SC package consisted of an introduction sheet, the four "Step" inserts, materials necessary to complete the PRUCAL diet analysis (9), and a SC reminder sheet with magnetic logo, all packaged in a simple pocket folder. This package, personalized with the patient's cholesterol levels and laboratory recheck date, would be given to the participant at the completion of the enrollment process.

The UC program had no special materials prepared and consisted of a counseling session lasting approximately one hour. During the session, information was presented on lowering cholesterol, focusing on the basic components of *Step One* dietary treatment (15). The dietitian was able to adjust the program depending on the client's background and concerns. Individuals enrolled in UC were told that they would receive a PRUCAL worksheet in approximately ten weeks and that it was to be completed and turned in when they returned for their follow-up lipid analysis. The UC participants were not contacted again and received no further intervention during this study.

Sample design. The minimum sample sizes required were calculated (16) based on the following considerations: an average day-to-day precision or coefficient of variation (CV) for repeated cholesterol measurements of eight per cent (17), average cholesterol level at entry of 260 mg/dl, a difference to be detected of 13 mg/dl, a power of 90%, and a 95% level of significance. Anticipating a dropout of 15% from the study groups, the sample size goals were set at 60 for both SC and UC. Eligible participants were recruited from male and female volunteers whose TC values were above 200 mg/dl and/or who had a TC/HDL-C ratio greater than 4.5. Individuals taking cholesterol-lowering medications were excluded from this study.

Once identified, individuals at risk were advised that they should schedule an appointment with the hospital's RD. At the start of the consultation, a brief description of SC was presented, and then a volunteer was given a personalized SC package (as described above) and asked to complete an enrollment and consent form. The entire process took less than 10 minutes.

Individuals were enrolled in UC at the conclusion of their scheduled consultation. They were also asked to complete an enrollment and consent form and to agree to complete a diet worksheet prior to their final lipid analysis. Randomization was accomplished by enrolling individuals in SC one week and then in UC the next. A preliminary diet analysis was not completed for the UC participants because, based on past experience, if other baseline values were equal, then the baseline dietary values for UC would not be significantly different from the initial SC values.

Data collection. The information collected at the start of the study from the SC and UC participants included anthropometric data, a complete lipid profile, behavioral factors, and prescription drug use. A diet analysis was completed for only the SC participants. The blood for the lipid analysis was obtained after a 12-hour fast, with the patient seated and the tourniquet removed. The hospital's laboratory had centrally supervised quality control, with lipid determinations standardized using Centers for Disease Control reference samples (18). Total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), and triglyceride (TG) values where measured, and the low density lipoprotein cholesterol (LDL-C) levels were calculated (19). At the 12-week point, weight and serum lipids were remeasured, and a final dietary analysis was completed for both study groups. For each dietary analysis, information on five dietary variables was recorded--total calories as a percentage of goal (%Cal) as determined by PRUCAL analysis, cholesterol as a percentage of maximum goal (%Chol) (300 mg/day), dietary fiber as a percentage of minimum goal (15 grams/1000 kcal), total fat as a percentage of calories (%Fat), and polyunsaturated/saturated fat (P/S) ratio.

Statistical analysis. Two primary endpoints, the change in TC and the change in the TC/HDL-C ratio, were selected during the design of this study to serve as indicators of program effectiveness (2,20). The data for the lipid analysis are presented at the baseline and at the 12-week point as the mean ± the standard error of the mean. While there may be a bimodal distribution for certain baseline values for males and females, most importantly HDL-C, we

chose to combine the data since we were primarily interested in the changes in lipid levels as an indication of program effectiveness and would be alerted to any significant gender effects by the statistical analysis (20-22). Still, caution would be advised in extrapolating the results of this study to one gender or a nonmilitary setting.

Preliminary analysis involved assessing the comparability of the treatment groups at the start of the study and then determining if there was a significant difference between each group's response to treatment. A two-sample *t-test* was used to assess the significance of these between group differences. A *Student's t-test* for paired data was used to assess the statistical significance of changes in blood lipids among subjects. The level of statistical significance was determined using a two-tailed test and a 5% level of significance (23).

When the preliminary analysis revealed a statistically significant change in the mean level of a serum lipid, multiple regression analysis was used to evaluate the relationship between the changes and several independent variables. The dependent variables used in the analysis were the change in TC, HDL-C, and TC/HDL-C ratio. For each dependent variable, the independent variables entered were treatment, gender, age, initial body mass index (BMI), prescription drug use, dietary fiber consumption, activity level, smoking status, %Fat, and P/S ratio. Step-wise multiple regression analyses were performed by computer using the SAS/STAT Release 6.03 (23). The Step-wise procedure was used so that the independent variable(s) remaining in the model would only be those that are statistically significant (α=0.05). Finally, analysis of covariance was used to determine if the significant differences detected by the two-sample "t" tests were actually due to treatment or perhaps to factors such as the age, gender, and/or initial BMI of subjects in the study.

RESULTS & DISCUSSION

This study revealed that both the SC and UC programs were associated with significant improvements in the average lipid profile of the participants, the magnitude of the changes were the same for males and females, and there was not a significant treatment effect.

Subject profiles. Baseline data are shown in Table 1. The sample sizes met design goals with only minimal drop-out--11.3% for SC and 8.3% for UC. Drop-outs were evenly split between

Table 1. Comparison of the Baseline Values[1] of Selected Variables for Self-CARE and Usual-Care

VARIABLE	SELF-CARE			USUAL-CARE		
	Total	Male	Female	Total	Male	Female
Patients (Start)	62	36	26	60	28	32
Drop-out	7	5	2	5	2	3
Patients (End)	55	31	24	55	26	29
AGE	53.6 ± 1.6	51.9 ± 2.3	55.9 ± 2.1	53.8 ± 1.6	53.5 ± 2.6	54.1 ± 2.0
BMI	25.3 ± 0.4	25.5 ± 0.5	25.0 ± 0.6	26.2 ± 0.5	26.8 ± 0.6	25.5 ± 0.7
TC mg/cl	258 ± 4.9	248 ± 5.1[a,b]	273 ± 8.5[a,c]	259 ± 4.7	247 ± 6.4[c,d]	269 ± 6.4[b,d]
LDL-C mg/cl	175 ± 4.6	170 ± 5.0	181 ± 8.4	173 ± 4.1	167 ± 5.5	177 ± 5.9
HDL-C mg/cl	46 ± 1.4	42 ± 1.6[a,b]	52 ± 2.3[a,c]	48 ± 1.9	41 ± 2.2[c,d]	54 ± 2.8[b,d]
TC/HDL-C Ratio	5.9 ± 0.2	6.1 ± .03	5.7 ± .03	5.8 ± 0.2	6.4 ± .03	5.3 ± .03

1 mean value ± standard error of the mean
mean values[a-d] in the same row sharing the same superscript are significantly different, $P<0.05$
BMI = body mass index (kg/m^2)
TC = total serum cholesterol
LDL-C = low density lipoprotein cholesterol
HDL-C = high density lipoprotein cholesterol

Table 2. Change in Values[1] of Selected Variables over Three Months.

Variable	N	Baseline	3-Months	Change
SELF-CARE				
TC mg/dl	55	259.6 ± 5.4	246.3 ± 6.2	-13.3 ± 3.6[a]
HDL-C mg/dl	55	46.4 ± 1.6	45.2 ± 1.6	-1.2 ± 1.1
TC/HDL-C	55	5.9 ± 0.2	5.8 ± 0.2	-0.13 ± 0.15
BMI	55	25.2 ± 0.5	24.7 ± 0.5	-0.45 ± 0.09[a]
LDL-C mg/dl	52	175.9 ± 5.1	165.0 ± 5.6	-10.9 ± 6.3[a]
USUAL-CARE				
TC mg/dl	55	259.1 ± 4.9	247.0 ± 4.7	-12.0 ± 4.6[a]
HDL-C mg/dl	55	47.9 ± 2.0	48.2 ± 2.0	+0.33 ± 0.8
TC/HDL-C	55	5.9 ± 0.2	5.5 ± 0.2	-0.37 ± 0.16[a]
BMI	55	26.1 ± 0.5	25.6 ± 0.5	-0.4 ± 0.1[a]
LDL-C mg/dl	52	172.7 ± 4.4	163.7 ± 4.4	-8.9 ± 5.6

1 mean value ± standard error of the mean
a significant difference by paired t test, $P<0.05$
BMI = body mass index (kg/m^2)
TC = total serum cholesterol
LDL-C = low density lipoprotein cholesterol
HDL-C = high density lipoprotein cholesterol

those who had serious medical or personal problems and those who were just not interested. The only significant difference between the SC and UC groups was that females had higher TC levels and, as anticipated, the females had significantly higher HDL-C levels than males (Table 1). Due to the higher TC levels of the females there was no significant difference between the TC/HDL-C ratios of males and females. The value of using the BMI is that it is a sensitive measure of obesity for both males and females which can use one scale (24). The baseline BMIs showed that, on average, the groups could be classified as mildly obese. While a large weight loss is not expected over only a three month period, the SC and UC participants experienced almost identical decreases in BMI, -0.45± 0.09 for SC and -0.4±0.1 for UC. These changes were significantly different from their respective baseline value, but not significantly different from one another (Table 2).

Dietary changes. The 24-hour diet records used in this study were intended to educate and to reinforce the SC program. They are not usually accurate enough to reveal any relationships between an individual's dietary intake and changes in serum lipids (25). In this study, because of the low values calculated, it also appears that portion sizes were underestimated, and that the dietary changes measured were only relative indicators of change. This observation appears to be correct, because while the decreases in BMI and serum lipids seem to correlate with changes in four of the five dietary variables recorded, no statistically significant relationships were found. Fiber intake did not change, while all other factors recorded did change significantly ($P<0.05$). The %Fat decreased from 32.5±9% to 28.0±8% for SC and to 30.8±8% for UC. The %Cal not only decreased from a baseline of 89% to 78% for SC and to 86% for UC, but the SC decrease was significantly greater than that for UC ($P< 0.05$). Finally, the %Chl decreased from 70% to 59% for SC and to 55% for UC, while the P/S ratio increased from 0.62±.4 to 0.76±.4 for SC and to 0.88±.4 for UC. These self-reported food intakes indicate that individuals were modifying their diets and demonstrate a dietary basis for the changes in lipid levels.

Blood lipids. The change in TC was significantly different from baseline for both SC and UC. The decrease was 13.3±3.6 mg/dl for SC and 12.0±4.6 for UC, approximately a 5% decrease for each program (Table 2). These decreases were not significantly different from one another, but are in line with the 5-7% decrease in TC one would expect from adoption of the AHA Step 1 Diet (26,27,28). Other changes noted were that the SC change for LDL-C was significantly

different from baseline, as was the change in TC/HDL-ratio for UC. The overall changes revealed in this study, while small, were beneficial.

The changes illustrate that on a short-term basis nutrition education appears to help decrease elevated cholesterol levels. However, if the HDL-C levels are to be increased, additional efforts should be made with regard to monounsaturated fats, weight control, smoking, and exercise. This is especially important as the inverse relationship between atherosclerosis and HDL-C levels has become firmly established (29,30).

The external validity of this study should be carefully considered. Given a different set of conditions, the results are sure to vary. In a companion study (31), carried out in a small clinic setting, where there was the direct involvement of the first author of this study and several of the physicians in the planning and promotion of SC, significantly better results were obtained. Also, the use of only one lipid analysis was a possible confounder (32). Regression to the mean may have influenced the results. However, this would not likely have been more of a factor in UC than in SC or vice versa. Laboratory precision and within-individual variability may have also influenced the magnitude of the results; however, the data still appear to support the value of these short-term interventions.

Another limit to this study is the lack of a control group. While this was originally planned, the hospital administrator did not want any individuals to go untreated. Also, an additional lipid analysis half-way through the program would have helped in determining adherence to the dietary protocol. Finally, more detailed instruction and practice on completing a 24-hour diet record or even a three-day record would have increased the value of the dietary data.

CONCLUSIONS

The results of this research show that the UC in this study helped individuals modify their serum cholesterol levels. Additionally, individuals following the SC program experienced an average reduction in TC that was at least equal to the UC improvements. After reviewing these findings, the conclusion is that the SC program, because of its self-study format and effective use of time and manpower, should be considered for expanded usage and long-term evaluation.

Future research should include long-term follow-up to examine maintenance of the initial changes. It should also experiment with expanded usage of SC, with distribution of the SC materials by the physician to improve timeliness and efficiency. A study that used the SC program as a targeting tool to direct individuals towards the follow-up program that would be most effective for their needs would be appropriate. Finally, and perhaps most importantly, the results of the SC and the UC programs should be compared to the changes in patients who are counseled only by their physician and receive no follow on care--only then will we be able to examine the true effectiveness of our educational interventions.

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